

APR 19 2006

**SUMMARY OF SAFETY AND EFFECTIVENESS**

*This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of the SMDA and 21 CFR 807.92.*

1. Submitter's name, address, telephone number, contact person, and date summary prepared:

Submitter: Irvine Biomedical, Inc.

2375 Morse Avenue

Irvine, CA 92614

Tel. (949) 851-3053

Contact: Dennis Hong

Regulatory Affairs Manager

Tel. (949) 271-1134

Date: March 18, 2006

2. Name of device, including trade name and classification name:

a. Trade/Proprietary Name: Inquiry™ Optima™ PLUS Steerable  
Electrophysiology Catheter

b. Classification names: Catheter, Electrode Recording

3. Identification of the predicate device or legally marketed device or devices to which substantial equivalence is being claimed:

Company: Irvine Biomedical, Inc.

Device: Inquiry Optima Steerable Electrophysiology Catheter

510(k): K042775

Date Cleared: November 4, 2004

4. A description of the device that is the subject of the 510(k), including explanation of how the device functions, basic scientific concepts, significant physical and performance characteristics (design, material, physical properties):

The Inquiry Optima PLUS Steerable Electrophysiology Catheter is a flexible, radiopaque catheter with a variable number of electrodes with the first electrode located at the distal tip and the other band electrodes following at predetermined distances. A connecting cable is used to connect the catheter to electrogram devices.

The catheter has a distal loop in a plane perpendicular to the catheter body. The circumferential shape or loop allows the electrophysiologist to record the potentials of cardiac structures without changing the position of the catheter. The catheter shaft and/or loop is steerable by manipulating the handle. The placement of the electrodes around the entire circumference of the distal loop and on the shaft of the catheter also assists the electrophysiologist during fluoroscopy with visualization. The distal loop shape is easily straightened with the thumb and forefinger to facilitate insertion into sheaths and introducers. Once the catheter is extended beyond the sheath, the catheter resumes its pre-formed shape.

The device is supplied sterile and is intended for single use only.

5. Statement of intended use:

The Inquiry Optima Catheter is a steerable electrophysiology catheter used for recording intracardiac signals and cardiac stimulation during diagnostic electrophysiology studies. The Optima catheters are to be used to map the atrial regions of the heart.

6. Statement of how the technological characteristics of the device compare to those of the predicate or legally marketed device.

The Inquiry Optima and Inquiry Optima PLUS Steerable Electrophysiology Catheters are intended for electrogram recording and stimulation during electrophysiological studies. The modification in adding four additional electrodes on the shaft of the Inquiry Optima PLUS catheter does not affect the intended use or scientific technology of the device.

7. Brief summary of non-clinical tests and results:

The test plan for the Inquiry Optima PLUS Steerable Electrophysiology Catheter was based on the guidance document "Electrode Recording Catheter Preliminary Guidance, Draft Version", March 1995. The test results indicated reliable performance when the device was used in accordance with the Instructions for Use. The Inquiry Optima PLUS catheter does not raise new issues of safety, effectiveness, or performance of the product.

8. Comparison Characteristics Between Inquiry Optima and Inquiry Optima PLUS Steerable EP Catheters

The Inquiry Optima Steerable EP Catheter and the Inquiry Optima PLUS Steerable EP catheter are both intended to be used for recording intracardiac signals and cardiac stimulation during diagnostic electrophysiology studies. In comparison to the Inquiry Optima Steerable EP Catheter, the Inquiry Optima PLUS Steerable EP Catheter has 4 additional electrodes. The similarities and differences between these catheters are tabularized below.

Product Description	Inquiry Optima Steerable EP Catheter (K042775)	Inquiry Optima PLUS Steerable EP Catheter
Type	Variable loop, steerable diagnostic catheter	Same
Size	7Fr Shaft, 4-5Fr Loop	Same
Usable Length	110cm	Same
Electrode Number on Loop	10 - 20 electrodes	20 electrodes
Size (width, diameter) of Electrode on Loop	0.6 mm – 1.0 mm width 4 Fr – 5 Fr diameter	1.0 mm width 5 Fr diameter
Electrode Number on Shaft	None	4 electrodes
Size (width, diameter) of Electrode on Shaft	None	1 mm width 7 Fr diameter
Distal Tip Electrode (length, diameter)	1 mm – 2 mm length, 4 Fr – 5 Fr diameter	1mm length 5 Fr diameter
Electrodes Material	Platinum / Iridium	Same
Electrode Profile	Each band has adhesive applied on both ends of the electrode	Same
Type of Curve	The catheter has a uni-direction 0-180° deflectable distal end, SM curve and an adjustable loop	Same
Loop Size	Adjustable, minimum is 15mm diameter, maximum is 25mm diameter	Same
Type of Catheter Outer Shaft	7 Fr size, non braided on distal, braided on proximal	Same
Material of Catheter Outer Shaft	Pebax	Same
Handle and Connector	The handle has a push/pull mechanism to steer the distal deflection curve and a rotating knob to adjust the distal loop diameter. The handle has a connector with 10 to 24 pins attached at the back of the handle.	The handle has a push/pull mechanism to steer the distal deflection curve and a rotating knob to adjust the distal loop diameter. The handle has a connector with 24 pins attached at the back of the handle.
Type of Conductor Wire	Electrodes use a Copper / Nickel Alloy	Same
Single-Use or Usable	Single-Use only	Same



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

APR 19 2006

Irvine Biomedical, Inc.  
c/o Mr. Dennis Hong  
Regulatory Affairs Manager  
2375 Morse Avenue  
Irvine, CA 92614

Re: K060757

Trade Name: Inquiry<sup>TM</sup> Optima<sup>TM</sup> PLUS Steerable Electrophysiology Catheter  
Regulation Number: 21 CFR 870.1220  
Regulation Name: Electrode Recording Catheter  
Regulatory Class: Class II (two)  
Product Code: DRF  
Dated: March 20, 2006  
Received: March 21, 2005

Dear Mr. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

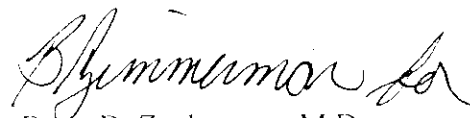
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman".

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

**Indications for Use**510(k) Number: K060757Device Name: Inquiry Optima PLUS Steerable Electrophysiology Catheter

Indications for Use: The Inquiry Optima Catheter is a steerable electrophysiology catheter used for recording intracardiac signals and cardiac stimulation during diagnostic electrophysiology studies. The Optima catheters are to be used to map the atrial regions of the heart.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
OF NEEDED)

Concurrence of CDRL Office of Device Evaluation (ODE)

B. J. Munnica  
(Division Sign)  
Division of Cardiovascular Devices  
510(k) Number K060757